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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

OGDEN JR, NICHOLUS

ART UNIT

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1796

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/722,008

Applicant(s)

TSAO ET AL.

Examiner

Necholus Ogden

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-4,6,8-10,12-14, 16-30 is/are pending in the application.
- 4a) Of the above claim(s) 25-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-4,6,8-10,12-14,16-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Response to Amendment

Claim Rejections - 35 USC § 112

Claims 21 and 23 contain the trademark/trade name poloxamer and tyloxapol in parenthesis and therefore the 35 USC 112 rejection is maintained.

1. Claims 1, 3-4, 6, 8-10, 12-14, 17-19 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hu et al (6,037,328) is withdrawn.

1. Claims 1, 3-4, 6, 8-10, 12-14, 17-19 are rejected under 35 U.S.C. 103(a) as obvious over Hu et al (6,037,328) in view of Schwind et al (2002/0155961).

Hu et al disclose a method and composition for rewetting and preventing deposits on contact lens comprising an effective amount of a glucose derivative, a tyloxapol and a nonionic surfactant (col. 2, lines 45-60). Hu et al specifically disclose surfactants such as poloxamers in an amount from 0.01 to 10% by weight (col. 4, lines 50-53); and tyloxapol (col. 4, lines 65-67). Hu et al further disclose viscosity builders (col. 5, lines 37-45); preservatives or antimicrobial agents such as PHMB in an amount from 0.00001 to about 0.0015 by weight (col. 6, lines 15-20); and buffers, stabilizers or isotonic agents such as glycerol in an amount of 2.5% (col. 6, lines 33-49) to comprise an osmolality of 225 to 400 mOsm/kg at a pH of 5 to 8 and buffers such as phosphates in an amount from 0.05 to 2.5% (col. 6, lines 49-59). Hu et al further include a sequestrant such as EDTA in an amount from 0.01 to 0.2% by weight (col. 6, lines 60-67). See Table I.

Hu et al is silent with respect to reducing the *C. albicans* within 15 minutes and having a log reduction of at least 1 or 1.5. However, it would have been

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obvious for the compositions of Hu to encompass the *C. albicans* in the requisite log reduction and time of contact because Hu et al teaches all of the claimed components in their requisite proportions, for the purpose of disinfecting and absent a showing to the contrary one of ordinary skill would expect similar contact lens cleaning and disinfecting characteristics.

2. Specifically, Hu is silent with respect to the sorbitol and dexpanthenol component.

Schwind et al disclose a lens care product comprising 5-20 g/l of dexpanthenol; 10 to 30 g/l of D-sorbitol; 0 to 5 g/l of sodium chloride or potassium chloride; 0.0005 to 0.05 g/l of PHMB; 0.1 to 2 g/l of EDTA; disodium phosphate buffers; water; a surface active substance; viscosifier; a pH value of 6 to 8 (see 0030-0032) and 0.072 g/l of disodium hydrogen phosphate (0039). Schwind et al further teach that the tonicity is measured in the range of 200 to 450 milliosmol (col. 1, 0007).

It would have been obvious to one of ordinary skill in the art to include the dexpanthenol and sorbitol components of Schwind et al to the compositions of Hu et al because Schwind et al teach that dexpanthenol guards against the appearance of dryness and has good cleansing action (0002) and Hu et al is concerned with preventing deposits on contact lens (see abstract). Therefore, absent a showing to the contrary, one of ordinary skill in the art would have been motivated to include the dexpanthenol for its intended purpose because only beneficial results would have been obtained.

With respect to the sorbitol component, Hu et al teach the inclusion of glycerol as tonicity agents (see above) and Schwind et al disclose sorbitol as a tonicity adjusting agent (0018) and Hu et al invite the use of tonicity agents. Therefore, one of ordinary skill in the art would have been motivated to include the sorbitol component for its intended purposes of adjusting the osmolality and further Hu et al invite the inclusion of tonicity agents. Accordingly, in the absence of a showing to contrary, one of ordinary skill would have been motivated to include the sorbitol component of Schwind et al to the compositions of Hu et al because only beneficial results would have been obtained.

3. Claim 20 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hu et al (6,037,328) in view of Groemminger et al (6,872,695).
4. Hu et al is relied upon as set forth above. Specifically, Hu et al is silent with respect to the pvp component.

Groemminger et al disclose a method of cleansing contact lens comprising a thickening agent such as PVP (col. 4, line 42); surfactants such as poloxamine and tyloxapol (col. 4, line 66 and col. 5, line 35); an antimicrobial such as PMHB in an amount from 0.00001 to 5%; osmolality-adjusting agent such as glycerol to provide osmolality of 270 mOsm/kg and a pH of 5-6 (col. 6, lines 26-59); a sequestering or chelating agent such as EDTA (col. 6, lines 60-62) and tonicity agents such as sodium chloride in amount from 0.01 to 2.5% (col. 7, lines 1-11).

Hu et al is silent with respect to the pvp component.

Specifically, Groemminger et al teach the use of polyvinyl pyrrolidone as a thickening agent or pseudoplastic (viscosity affecting) (col. 4, line 28-42) and Hu et al require the use of substances that affect the viscosity (col. 5, lines 33-45). Therefore, one of ordinary skill in the contact lens art would have included PVP to the compositions of Hu et al to affect the viscosity of the contact lens composition as suggested by Groemminger et al for the purpose of affecting the shear liquification of gel upon blinking (col. 4, lines 27-29).

5. Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al (6,037,328) in view of Schwind et al (2002/0155961), and further in view of Groemminger et al (6,872,695).

Hu et al, Schwind et al and Groemminger et al are relied upon as set forth above. Specifically, Hu et al is silent with respect to the dexpanthenol, sorbitol and pvp components.

It would have been obvious to one of ordinary skill in the art to include the dexpanthenol and sorbitol components of Schwind et al to the compositions of Hu et al because Schwind et al teach that dexpanthenol guards against the appearance of dryness and has good cleansing action (0002) and Hu et al is concerned with preventing deposits on contact lens (see abstract). Therefore, absent a showing to the contrary, one of ordinary skill in the art would have been motivated to include the dexpanthenol for its intended purpose because only beneficial results would have been obtained.

With respect to the sorbitol component, Hu et al teach the inclusion of glycerol as tonicity agents (see above) and Schwind et al disclose sorbitol as a

tonicity adjusting agent (0018) and Hu et al invite the use of tonicity agents. Therefore, one of ordinary skill in the art would have been motivated to include the sorbitol component for its intended purposes of adjusting the osmolality and further Hu et al invite the inclusion of tonicity agents. Accordingly, in the absence of a showing to contrary, one of ordinary skill would have been motivated to include the sorbitol component of Schwind et al to the compositions of Hu et al because only beneficial results would have been obtained.

Specifically, Groemminger et al teach the use of polyvinyl pyrrolidone as a thickening agent or pseudoplastic (viscosity affecting) (col. 4, line 28-42) and Hu et al require the use of substances that affect the viscosity (col. 5, lines 33-45). Therefore, one of ordinary skill in the contact lens art would have include PVP to the compositions of Hu et al to affect the viscosity of the contact lens composition as suggested by Groemminger et al for the purpose of affecting the shear liquification of gel upon blinking (col. 4, lines 27-29), absent a showing to the contrary.

Accordingly, since each of the prior art of record teach contact lens cleansing compositions comprising many of the same well known components, the artisan of ordinary skill would have motivated to try similar or equivalent component with the expectation that synergistic and/or beneficial results would have been obtained.

Response to Arguments

6. Applicant's arguments filed 1-17-2008 have been fully considered but they are not persuasive.

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7. Applicant argues that Hu and Schwind et al do not teach the claimed components and reducing the *C. albicans* within 15 minutes and having a log reduction of at least 1 or 1.5.

The examiner contends that Hu et al is silent with respect to reducing the *C. albicans* within 15 minutes and having a log reduction of at least 1 or 1.5. However, it would have been obvious for the compositions of Hu to encompass the *C. albicans* in the requisite log reduction and time of contact because Hu et al teaches all of the claimed components in their requisite proportions, for the purpose of disinfecting and absent a showing to the contrary one of ordinary skill would expect similar contact lens cleaning and disinfecting characteristics.

8. Applicant argues that Groemminger does not provide further teaching that would render the invention obvious.

9. The examiner contends that Groemminger specifically teaches that PVP is used as a viscosity improving agent and Hu invites the inclusion of viscosity agents, therefore, it would have been obvious to include the PVP ingredient for its intended purpose and absent a showing to the contrary.

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. ___, 2007 WL 1237837, at *12 (2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Double Patenting

Applicant argues that none of the patents or provisional application recited and rejected for ODP comprises the ingredients as set forth herein and claimed.

The examiner contends that applicant's describes his most limited comprehensive claim and does set forth claim 1 which is broader in scope to argue his point. It is the broadest claim that overlaps in scope with the patents and provision applications. Moreover, many patents and provisional application comprise broad limitations and descriptions that read on applicant's claims. Therefore, the rejection is maintained for reasons disclosed herein.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Necholas Ogden whose telephone number is 571-272-1322. The examiner can normally be reached on M-Thu.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Necholus Ogden/
Primary Examiner
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4-24-2008

Application Number**Application/Control No.**

10/722,008

Examiner

Necholus Ogden

**Applicant(s)/Patent under
Reexamination**

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